



## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-372]

### Exempt Chemical Preparations Under the Controlled Substances Act

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Order with opportunity for comment.

**SUMMARY:** The applications for exempt chemical preparations received by the Drug Enforcement Administration (DEA) between September 1, 2020, and March 31, 2021, as listed below, were accepted for filing and have been approved or denied as indicated.

**DATES:** Interested persons may file written comments on this order in accordance with 21 CFR 1308.23(e). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA-372” on all correspondence, including any attachments.

*Electronic comments:* DEA encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a comment tracking number, your comment has been successfully submitted and there is

no need to resubmit the same comment.

*Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** Terrence L. Boos, Ph.D., Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-8201.

**SUPPLEMENTARY INFORMATION:**

**Posting of Public Comments**

Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first

paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at <http://www.regulations.gov> for easy reference.

### **Legal Authority**

Section 201 of the Controlled Substances Act (CSA) (21 U.S.C. 811) authorizes the Attorney General, by regulation, to exempt from certain provisions of the CSA certain compounds, mixtures, or preparations containing a controlled substance, if he finds that such compounds, mixtures, or preparations meet the requirements detailed in 21 U.S.C. 811(g)(3)(B).<sup>1</sup> DEA regulations at 21 CFR 1308.23 and 1308.24 further detail the criteria by which DEA's Assistant Administrator may exempt a chemical preparation or mixture from certain provisions of the CSA. The Assistant Administrator may, pursuant to 21 CFR 1308.23(f), modify or revoke the criteria by which exemptions are granted and modify the scope of exemptions at any time.

### **Exempt Chemical Preparation Applications Submitted Between September 1, 2020, and March 31, 2021**

The Assistant Administrator received applications between September 1, 2020,

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<sup>1</sup> This authority has been delegated from the Attorney General to the Administrator of the DEA by 28 CFR 0.100, and subsequently redelegated to the Deputy Assistant Administrator pursuant to 28 CFR 0.104 and Section 7 of the appendix to subpart R of part 0.

and March 31, 2021, requesting exempt chemical preparation status detailed in 21 CFR 1308.23. Pursuant to the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23, the Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart I below is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or animal and either: (1) contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse; or (2) contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration that the preparation or mixture does not present any potential for abuse and, if the preparation or mixture contains a narcotic controlled substance, is formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have ill effects, if abused, and so that the narcotic substance cannot in practice be removed.

Accordingly, pursuant to 21 U.S.C. 811(g)(3)(B), 21 CFR 1308.23, and 21 CFR 1308.24, the Assistant Administrator has determined that each of the chemical preparations or mixtures generally described in Chart I below and specifically described in the application materials received by DEA is exempt, to the extent described in 21 CFR 1308.24, from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003, and 1004 (21 U.S.C. 822-823, 825-829, and 952-954) of the CSA, and 21 CFR 1301.74, as of the date that was provided in the approval letters to the individual requesters.

### **Scope of Approval**

The exemptions are applicable only to the precise preparation or mixture described in the application submitted to DEA in the form(s) listed in this order and only for those

above mentioned sections of the CSA and the CFR. In accordance with 21 CFR 1308.24(h), any change in the quantitative or qualitative composition of the preparation or mixture, or change in the trade name or other designation of the preparation or mixture after the date of application requires a new application. The requirements set forth in 21 CFR 1308.24(b)-(e) apply to the exempted materials. In accordance with 21 CFR 1308.24(g), DEA may prescribe requirements other than those set forth in 21 CFR 1308.24(b)-(e) on a case-by-case basis for materials exempted in bulk quantities. Accordingly, in order to limit opportunity for diversion from the larger bulk quantities, DEA has determined that each of the exempted bulk products listed in this order may only be used in-house by the manufacturer, and may not be distributed for any purpose, or transported to other facilities.

Additional exempt chemical preparation requests received between September 1, 2020, and March 31, 2021, and not otherwise referenced in this order, may remain under consideration until DEA receives additional information required, pursuant to 21 CFR 1308.23(d), as detailed in separate correspondence to individual requesters. DEA's order on such requests will be communicated to the public in a future *Federal Register* publication.

DEA also notes that these exemptions are limited to exemption from only those sections of the CSA and the CFR that are specifically identified in 21 CFR 1308.24(a). All other requirements of the CSA and the CFR apply, including registration as an importer as required by 21 U.S.C. 957.

**Chart I**

<b>Supplier</b>	<b>Product Name</b>	<b>Form</b>	<b>Application Date</b>
Aalto Scientific, Ltd.	Cal Ver FLQ Drugs of Abuse for Roche Systems Level 1	Glass vial: 3 mL	2/23/2021
Aalto Scientific, Ltd.	Cal Ver FLQ Drugs of Abuse for Roche Systems Level 2	Glass vial: 3 mL	2/23/2021
Aalto Scientific, Ltd.	Cal Ver FLQ Drugs of Abuse for Roche Systems Level 3	Glass vial: 3 mL	2/23/2021
Aalto Scientific, Ltd.	Linearity FD Fertility Siemens Centaur	Kit: 10 vials; 3 mL each	3/29/2021
Aalto Scientific, Ltd.	Linearity FLQ TDM for Ortho Vitros	Kit: 5 dropper bottles; 4 mL each	3/31/2021
Agilent Technologies	Custom Organic Std – 11 analytes at 250 µg/mL	Amber ampule: 1 mL	2/19/2021
Cambridge Isotope Laboratories, Inc.	Labeled Steroid Mix 40X Set S NSK-S-40X	Glass vial: 1 mL	3/1/2021
Cambridge Isotopes Laboratories, Inc.	Delta-9- tetrahydrocannabinol (THC) Unlabeled (95% CP), 1000 µg/mL in methanol (0.1%)	Glass ampule: 1.2 mL	2/19/2021
Cambridge Isotopes Laboratories, Inc.	Delta-9-Trans-tetrahydrocannabinol (THC) (Methyl-D3, 98%), 100 µg/mL in methanol (0.01%)	Glass ampule: 1.2 mL	2/19/2021
Cambridge Isotopes Laboratories, Inc.	Testosterone (2,3,4-13C3, 99%) 100 µg/mL in acetonitrile	Glass ampule: 1 mL	2/19/2021
Cayman Chemical Company	(+/-)-11-hydroxy-d8-THC (CRM) 1 mg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	(+/-)-11-hydroxy-d8-THC (CRM) 1 mg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	(+/-)-11-hydroxy-d8-THC (CRM) 100 µg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	(+/-)-11-hydroxy-d8-THC (CRM) 100 µg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	Benzoylcegonine (CRM) 1 mg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Benzoylcegonine (CRM) 100 µg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Benzoylcegonine-d3 (CRM) 1 mg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Benzoylcegonine-d3 (CRM) 100 µg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Cocaine-d3 (CRM) 1 mg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Cocaine-d3 (CRM) 100 µg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	D8-THCB (CRM) 100 µg/mL, 1 mL acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	D8-THCB (CRM) 1 mg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021

Cayman Chemical Company	D8-THCB (CRM) 1 mg/ml, 1 mL methanol	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	D8-THCB (CRM) 100 µg/mL, 1 mL methanol	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	D8-THCP (CRM) 1 mg/ml, 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	D8-THCP (CRM) 1 mg/ml, 1 mL methanol	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	D8-THCP (CRM) 100 µg/mL, 1 mL acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	D8-THCP (CRM) 100 µg/mL, 1 mL methanol	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	D9-THC Acetate (CRM) 1 mg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	D9-THC Acetate (CRM) 1 mg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	D9-THC Acetate (CRM) 100 µg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	D9-THC Acetate (CRM) 100 µg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Norfentanyl-d5 (CRM) 1 mg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Norfentanyl-d5 (CRM) 100 µg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 5 (CRM) 100 µg/mL 0.5 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 0.5 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 5 (CRM) 100 µg/mL 0.5 mL in acetonitrile	Glass ampule: 0.5 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 1 mg/mL 0.5 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 0.5 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 1 mg/mL 0.5 mL in acetonitrile	Glass ampule: 0.5 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 1 mg/mL 1 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 1 mg/mL 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 100 µg/mL 1 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 100 µg/mL 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 250 µg/mL 0.5 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 0.5 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 250 µg/mL 0.5 mL in acetonitrile	Glass ampule: 0.5 mL	2/3/2021

Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 250 µg/mL 1 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 250 µg/mL 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 500 µg/mL 0.5 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 0.5 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 500 µg/mL 0.5 mL in acetonitrile	Glass ampule: 0.5 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 500 µg/mL 1 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 6 (CRM) 500 µg/mL 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 1 mg/mL 0.5 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 0.5 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 1 mg/mL 0.5 mL in acetonitrile	Glass ampule: 0.5 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 1 mg/mL, 1 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 1 mg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 100 µg/mL 0.5 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 0.5 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 100 µg/mL 0.5 mL in acetonitrile	Glass ampule: 0.5 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 100 µg/mL, 1 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 100 µg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 250 µg/mL 0.5 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 0.5 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 250 µg/mL 0.5 mL in acetonitrile	Glass ampule: 0.5 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 250 µg/mL, 1 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 250 µg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 500 µg/mL, 1 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7 (CRM) 500 µg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/3/2021
Cayman Chemical Company	Phytocannabinoid Acids Mixture 7(CRM) 500 µg/mL 0.5 mL in 1:99 DIPEA: acetonitrile with 0.05% ascorbic acid	Glass ampule: 0.5 mL	2/23/2021



Cayman Chemical Company	Phytocannabinoid Acids Mixture 7(CRM) 500 µg/mL 0.5 mL in acetonitrile	Glass ampule: 0.5 mL	2/3/2021
Cayman Chemical Company	Psilocin (CRM) 1 mg/mL in Acetonitrile	Glass ampule: 1.0 mL	2/24/2021
Cayman Chemical Company	Psilocin (CRM) 100 µg/mL in Acetonitrile	Glass ampule: 0.5 mL	2/24/2021
Cayman Chemical Company	Psilocin-d10 (CRM) 1 mg/mL in Acetonitrile	Glass ampule: 1.0 mL	2/24/2021
Cayman Chemical Company	Psilocin-d10 (CRM) 100 µg/mL in Acetonitrile	Glass ampule: 1.0 mL	2/24/2021
Cayman Chemical Company	Psilocin-d4 (CRM) 1 mg/mL in Acetonitrile	Glass ampule: 1.0 mL	2/24/2021
Cayman Chemical Company	Psilocin-d4 (CRM) 100 µg/mL in Acetonitrile	Glass ampule: 1.0 mL	2/24/2021
Cayman Chemical Company	Psilocybin (CRM) 1 mg/mL in 1:1 Acetonitrile:H2O	Glass ampule: 1.0 mL	2/24/2021
Cayman Chemical Company	Psilocybin (CRM) 100 µg/mL in 1:1 Acetonitrile:H2O	Glass ampule: 0.5 mL	2/24/2021
Cayman Chemical Company	Psilocybin-d10 (CRM) 1 mg/mL in 1:1 Acetonitrile:H2O	Glass ampule: 1.0 mL	2/24/2021
Cayman Chemical Company	Psilocybin-d10 (CRM) 100 µg/mL in 1:1 Acetonitrile:H2O	Glass ampule: 1.0 mL	2/24/2021
Cayman Chemical Company	Psilocybin-d4 (CRM) 1 mg/mL in 1:1 Acetonitrile:H2O	Glass ampule: 0.5 mL	2/24/2021
Cayman Chemical Company	Psilocybin-d4 (CRM) 100 µg/mL in 1:1 Acetonitrile:H2O	Glass ampule: 0.5 mL	2/24/2021
Cayman Chemical Company	U-47700 (CRM) 1 mg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	U-47700 (CRM) 100 µg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	U-47700-d6 (CRM) 1 mg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cayman Chemical Company	U-47700-d6 (CRM) 100 µg/mL, 1 mL in methanol	Glass ampule: 1 mL	2/23/2021
Cerilliant Corporation	(-)-delta8-THC-D3	Glass ampule: 1 mL	1/26/2021
Cerilliant Corporation	4-Methyl-alpha-pyrrolidinobutophenone HCl (MPBP HCl) (1.0 mg/mL)	Glass ampule: 1 mL	3/4/2021
Cerilliant Corporation	Tetrahydrocannabivarin-D5 (THCV-D5)	Glass ampule: 1 mL	1/26/2021
Cerilliant Corporation	Tetrahydrocannabivarinic acid-D5 (THCVA-D5)	Glass ampule: 1 mL	1/26/2021
Immunalysis Corporation	AMP/6-AM Oral Fluid Calibrator 1	Amber vial: 10 mL	2/10/2021
Immunalysis Corporation	AMP/6-AM Oral Fluid Calibrator 2	Amber vial: 10 mL	2/10/2021
Immunalysis Corporation	AMP/6-AM Oral Fluid Calibrator 3	Amber vial: 10 mL	2/10/2021

Immunalysis Corporation	AMP/6-AM Oral Fluid Calibrator 4	Amber vial: 10 mL	2/10/2021
Immunalysis Corporation	AMP/6-AM Oral Fluid Set	Kit: 2 vials, 10 mL each	2/10/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 202 Kit 250 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 203 Kit 500 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 204 Kit 1000 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 205 Kit 250 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 206 Kit 500 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 207 Kit 1000 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 214 Kit 250 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 214 Kit 250 µg/mL in Acetonitrile	1 Kit: 2 vials x 0.4 mL	10/9/2020
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 215 Kit 500 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 215 Kit 500 µg/mL in Acetonitrile	1 Kit: 2 vials x 0.4 mL	10/9/2020
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 216 Kit 1000 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 216 Kit 1000 µg/mL in Acetonitrile	1 Kit: 2 vials x 0.4 mL	10/9/2020
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 250 Kit 1000 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acid/Neutrals Mixture 250 Kit 1000 µg/mL in Acetonitrile	1 Kit: 2 vials x 0.4 mL	10/9/2020
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 184 1000 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 185 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 186 250 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 194 250 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 195 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 200 1000 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 210 250 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 210 250 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	10/9/2020

LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 211 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 211 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	10/9/2020
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 212 1000 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Acids Mixture 212 1000 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	10/9/2020
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 187 100 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 188 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 189 1000 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 190 50 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 191 100 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 192 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 193 1000 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 197 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 198 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 213 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 254 250 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 254 250 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	10/9/2020
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 255 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 255 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	10/9/2020
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 256 250 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 256 250 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/10/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 257 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 257 500 µg/mL in Acetonitrile	Amber ampule: 0.4 mL	3/10/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 258 Kit 250 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/31/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 258 Kit 250 µg/mL in Acetonitrile	1 Kit: 2 vials x 0.4 mL	3/10/2021

LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 259 Kit 500 µg/mL in Acetonitrile	1 kit: 2 vials x 0.4 mL	3/19/2021
LGC - Dr. Ehrenstorfer	Cannabinoids Mixture 259 Kit 500 µg/mL in Acetonitrile	1 Kit: 2 vials x 0.4 mL	3/10/2021
LGC - Dr. Ehrenstorfer	Custom Δ9-Tetrahydrocannabivarin (THCV) 1000 ug/mL in Acetonitrile	Amber ampule: 1 mL	1/19/2021
LGC - Dr. Ehrenstorfer	Δ9-Tetrahydrocannabivarinic acid (THCVA) 100 ug/mL in Acetonitrile	Amber ampule: 1 mL	3/10/2021
o2si smart solutions	Chloral Hydrate 1000 µg/mL in methanol	Amber ampule: 1 mL	3/24/2021
o2si smart solutions	Custom Pharmaceutical Mixture CCV 16-0260, 10.0 µg/mL, 300 µL with a 2 mL silanized vial (ISO17034)	Amber ampule: 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture ICV (second source), 16-0260, 10.0 µg/mL, 300 µL with a 2 mL silanized vial (ISO17034)	Amber ampule: 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture Level #1, 16-0260, 0.3 µg/mL, 300 µL with a 2 mL silanized vial (ISO17034)	Amber ampule: 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture Level #2, 16-0260, 1.0 µg/mL, 300 µL with a 2 mL silanized vial (ISO17034)	Amber ampule: 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture Level #3, 16-0260, 5.0 µg/mL, 300 µL with a 2 mL silanized vial (ISO17034)	Amber ampule: 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture Level #4, 16-0260, 10.0 µg/mL, 300 µL with a 2 mL silanized vial (ISO17034)	Amber ampule: 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture Level #5, 16-0260, 25.0 µg/mL, 300 µL with a 2 mL silanized vial (ISO17034)	Amber ampule: 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture Level #6, 16-0260, 50.0 µg/mL, 300 µL with a 2 mL silanized vial (ISO17034)	Amber ampule: 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture Level #7, 16-0260, 100.0 µg/mL, 300 µL with a 2 mL silanized vial (ISO17034)	Amber ampule: 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture Level #8, 16-0260, 250.0 µg/mL, 300 µL with a 2 mL silanized vial (ISO17034)	Amber ampule: 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture Calibration Kit 16-0260, (2 x G34-140260-98)	1 kit; 26 amber ampules x 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture Calibration Pack 16-0260, 13 x 1 ml	1 pack; 13 amber ampules x 300 µL	3/1/2021
o2si smart solutions	Custom Pharmaceutical Mixture LCS, 16-0260, 10.0 ug/mL, 1 mL with a 2 ml Silanized Vial (ISO17034)	Amber ampule: 1 mL	3/1/2021
Research Triangle Institute	0584, 7232, 6089, 8785, 7227, 8588, 7541, 4336, 1817, 0737, 5340, 2985, 8470, 3501, 7362, 6850, 5497, 4097, 2479, 1536, 7431, 9541, 1585, 8534, 2113, 9789, 2482, 1013, 1483, 8092, 6365, 2209, 5434, 4035, 9222, 9674, 5622, 3806, 1798, 9820	HDPE tubes: 5 mL	3/11/2021
Research Triangle Institute	3370, 1411, 5883, 5713, 8800, 3630, 8683, 4541, 8161, 0359, 9704, 2184,	HDPE tubes: 5 mL	3/11/2021

	0341, 2901, 0790, 6548, 3466, 0352, 5288, 8594, 0279, 8762, 3687, 2819, 8743, 7197, 5064, 0199, 1609, 8643, 6467, 2245, 0706, 0147, 6876, 3732, 9314, 1059, 8245, 8685		
Research Triangle Institute	4118, 3472, 9120, 3742, 9323, 4475, 5116, 7455, 3780, 9052, 4910, 2630, 6141, 9351, 5220, 2730, 6408, 3560, 4063, 0427, 0669, 8350, 9163, 6359, 0113, 1893, 4552, 2951, 1357, 8372, 9203, 3150, 9587, 9290, 4399, 2454, 2468, 7560, 6645, 8756	HDPE tubes: 5 mL	3/11/2021
Research Triangle Institute	4761, 2869, 4267, 9207, 1568, 8723, 7042, 6810, 0605, 7181, 8624, 0015, 5050, 7046, 3626, 7515, 9023, 8821, 6767, 0861, 0689, 5934, 2105, 2006, 1040, 5645, 2749, 7908, 9154, 8450, 5251, 6608, 3152, 9027, 2731, 7530, 1329, 0320, 5833, 7580	HDPE tubes: 5 mL	3/11/2021
Research Triangle Institute	4946, 2135, 7589, 456, 2617, 2224, 5066, 4134, 9514, 0206, 2691, 2807, 1571, 2201, 0943, 6995, 1299, 3729, 9561, 2552, 1248, 7138, 1634, 0813, 6352, 3567, 2017, 6701, 6915, 4448, 1967, 3179, 2480, 5144, 8826, 5515, 0949, 6109, 4040, 8632	HDPE tubes: 5 mL	3/11/2021
Research Triangle Institute	6673, 1920, 9080, 9040, 1769, 9824, 8015, 4813, 1535, 4285, 5824, 7430, 3338, 2989, 2743, 1537, 6009, 4808, 0243, 7097, 5533, 6638, 3414, 8238, 2573, 6806, 3959, 7896, 3448, 5652, 5273, 1341, 1063, 6664, 9471, 7136, 3571, 8916, 8617, 8946	HDPE tubes: 5 mL	3/11/2021
Research Triangle Institute	7155, 9763, 5721, 5161, 0009, 8118, 7420, 0527, 4415, 6892, 6896, 8988, 6477, 9903, 6688, 0292, 9380, 4579, 9601, 7337, 1518, 2189, 8886, 8880, 6963, 9446, 7721, 9988, 7688, 2525, 4017, 6826, 3426, 4128, 6270, 4207, 0646, 5741, 6086, 0528	HDPE tubes: 5 mL	3/11/2021
Research Triangle Institute	7938, 8287, 2990, 7693, 6858, 5995, 1929, 3740, 4461, 0196, 4271, 9853, 5024, 6378, 3409, 2702, 7629, 6194, 4553, 2871, 0203, 4812, 7073, 0834, 2732, 1841, 9545, 5063, 5062, 6234, 0210, 9740, 9472, 9938, 5122, 8677, 3537, 5198, 5977, 8203	HDPE tubes: 5 mL	3/11/2021
Research Triangle Institute	8497, 8384, 3406, 0324, 6930, 3165, 1564, 8858, 4968, 8840, 7836, 9412, 9009, 0109, 0695, 0923, 0912, 3228, 6855, 5103, 8580, 4499, 8347, 7831, 8420, 2875, 6778, 6680, 9098, 1987, 6813, 6572, 9943, 6165, 0958, 5884, 1843, 2991, 3191, 1151	HDPE tubes: 5 mL	3/11/2021
Research Triangle Institute	9493, 8564, 6768, 1670, 2733, 0560, 7822, 7495, 1290, 4534, 6583, 3937, 6596, 2599, 9164, 5702, 8328, 9643, 5747, 1923, 0976, 3416, 1445, 3834, 3069, 7609, 6580, 3945, 1726, 2891, 4325, 8970, 7248, 1981, 3906, 0989, 3648, 7769, 4122, 9050	HDPE tubes: 5 mL	3/11/2021

Restek Corporation	Cannabinoids Acids 7 Standard	Glass ampule: 1.3 mL	3/31/2021
UTAK Laboratories, Inc.	AED II MR Serum Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	Amphetamines Panel Level 1 Urine Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	Amphetamines Panel Level 2 Urine Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	Benzodiazepines Hydrolysis QC Urine Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Benzodiazepines Plus 100 ng/mL Urine Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	Benzodiazepines Plus 100 ng/mL Whole Blood Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	Benzodiazepines Plus 400 ng/mL Urine Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	DAU IA 1 Urine Control	Kit: 4 bottles, 10 mL each	11/20/2020
UTAK Laboratories, Inc.	DAU IA 2 Urine Control	Kit: 4 bottles, 10 mL each	11/20/2020
UTAK Laboratories, Inc.	DAU IA 3 Urine Control	Kit: 4 bottles, 10 mL each	11/20/2020
UTAK Laboratories, Inc.	DAU IA 4 Urine Control	Kit: 4 bottles, 10 mL each	11/20/2020
UTAK Laboratories, Inc.	DAU IA 5 Urine Control	Kit: 4 bottles, 10 mL each	11/20/2020
UTAK Laboratories, Inc.	DHEA Plus High Serum Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	DHEA Plus Low Serum Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Drugs of Abuse 200% Cutoff SMX Oral Fluid Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Drugs of Abuse 50% Cutoff SMX Oral Fluid Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Drugs of Abuse Cutoff SMX Oral Fluid Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Drugs of Abuse Level 2 Whole Blood Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	Miscellaneous Panel Level 1 Urine Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	Miscellaneous Panel Level 2 Urine Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	Opiates Hydrolysis QC Urine Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Pentobarbital Serum Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	STABBS Negative Serum Control	Kit: 5 bottles, 5 mL each	11/20/2020

UTAK Laboratories, Inc.	STABBS Positive Serum Control	Kit: 5 bottles, 5 mL each	11/20/2020
UTAK Laboratories, Inc.	Steroids Level 1 SMX Serum Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Steroids Level 2 SMX Serum Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Steroids Level 3 SMX Serum Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Steroids Level 4 SMX Serum Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Tapentadol Hydrolysis QC Urine Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Urine Drug Screen Urine Control	Kit: 5 bottles, 10 mL each	11/20/2020
UTAK Laboratories, Inc.	Z Drugs Plus Level 1 Urine Control	Kit: 5 bottles, 3 mL each	11/20/2020
UTAK Laboratories, Inc.	Z Drugs Plus Level 2 Urine Control	Kit: 5 bottles, 3 mL each	11/20/2020
Xvivo Perfusion	Supplemented XVIVO Heart Solution (SXHS)	Glass vial: 10 mL	9/11/2020
Xvivo Perfusion	XVIVO Heart Perfusion System (XHPS)	Kit: Heart Box, Disposable, Supplemented Soln.	9/11/2020

The Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart II below is not consistent with the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23. Accordingly, the Assistant Administrator has determined that the chemical preparations or mixtures generally described in Chart II below and specifically described in the application materials received by DEA, are not exempt from application of any part of the CSA or from application of any part of the CFR, with regard to the requested exemption pursuant to 21 CFR 1308.23, as of the date that was provided in the determination letters to the individual requesters.

## Chart II

Supplier	Product Name	Form	Application Date
Cambridge Isotopes Laboratories, Inc.	Delta-9-tetrahydrocannabinol (THC) unlabeled (Chemical Purity 95%), 5 mg	Glass ampule: 5 mg	2/19/2021
Cambridge Isotopes Laboratories, Inc.	Delta-9-tetrahydrocannabinol (THC) unlabeled (Chemical Purity 95%), 0.5 mg	Glass ampule: 0.5 mg	2/19/2021
Cambridge Isotopes Laboratories, Inc.	Delta-9-tetrahydrocannabinol (THC) unlabeled (Chemical Purity 95%), 1 mg	Glass ampule: 1 mg	2/19/2021
Cambridge Isotopes Laboratories, Inc.	Delta-9-tetrahydrocannabinol (THC) unlabeled (Chemical Purity 95%), 10 mg	Glass ampule: 10 mg	2/19/2021
Cambridge Isotopes Laboratories, Inc.	Delta-9-Trans-tetrahydrocannabinol (THC) (Methyl-D3, 98%), 5 mg	Glass ampule: 5 mg	2/19/2021
Cambridge Isotopes Laboratories, Inc.	Delta-9-Trans-tetrahydrocannabinol (THC) (Methyl-D3, 98%), 0.5 mg	Glass ampule: 0.5 mg	2/19/2021
Cambridge Isotopes Laboratories, Inc.	Delta-9-Trans-tetrahydrocannabinol (THC) (Methyl-D3, 98%), 1 mg	Glass ampule: 1 mg	2/19/2021
Cambridge Isotopes Laboratories, Inc.	Delta-9-Trans-tetrahydrocannabinol (THC) (Methyl-D3, 98%), 10 mg	Glass ampule: 10 mg	2/19/2021
Cayman Chemical Company	Clonazepam (CRM) 1 mg/mL, 1 mL in acetonitrile	Glass ampule: 1 mL	2/23/2021
LGC - Dr. Ehrenstorher	$\Delta^9$ -Tetrahydrocannabivarin 10,000 mg/L Parent stock in Methanol- NOT FOR SALE	Boston Round, Amber glass: 14 mL	1/19/2021
LGC-Dr. Ehrenstorfer	Delta-9-THC 10000 $\mu$ g/mL in Methanol	Amber ampule: 2 mL	2/16/2021

### Opportunity for Comment

Pursuant to 21 CFR 1308.23(e), any interested person may submit written comments on or objections to any chemical preparation in this order that has been approved or denied as exempt. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Assistant Administrator will immediately suspend the effectiveness of any applicable part of this order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Assistant Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.



**Approved Exempt Chemical Preparations are Posted on the DEA's Web site**

A list of all current exemptions, including those listed in this order, is available on the DEA's Web site at

[http://www.DEAdiversion.usdoj.gov/schedules/exempt/exempt\\_chemlist.pdf](http://www.DEAdiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf). The dates of applications of all current exemptions are posted for easy reference.

**William T. McDermott,**  
*Assistant Administrator.*

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